REMARKS

Formal Matters

Claims 1-28 are pending after entry of the amendments set forth herein. Claims 1, 6, 11, 12,16, 21 –28 have been amended.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached is captioned **"VERSION WITH MARKINGS TO SHOW CHANGES MADE."**

Rejection under 35 USC §112

Claims 6-20 were rejected as indefinite. The examiner queried whether light passes through an interfermometer in (former) steps (a) and (b) or in each of the steps. Applicants have addressed the Examiner's concern regarding the claim by way of amendment of claim 6, impacting each of claims 7-20 dependent there from.

The "proviso" of claim 6 believed to be the root of the Examiner's enquiry has been deleted in favor of simply requiring that each of the light beams pass through an interferometer one time. Accordingly, it is believed that the content and scope of claims 6-20 as amended are sufficiently definite that the rejection under §112 should be withdrawn.

Rejections under 35 USC §102

Claims 1-10, 12, 13 and 21-28 in view of Mattson, et al.

It is believed that Mattson does not disclose use of the system described therein in connection with a sample of low transmissivity. By way of amendment to claims 1 and 6, claims 1-20 have been clarified as requiring use of such a sample in the methods described.

As to system claims 21-28, Matson, again, fails to anticipate the claimed subject matter. Claim 28 requires the presence of a sample of low transmissivity – which is not seen in the reference. Further, Mattson fails to disclose anything regarding the nature of the reference as required of claims 25-27. In Mattson, the reference cell is merely described as containing a known substance. Col. 5, lns. 15-18.

As to claims 21-28, it is of paramount importance to recognize the fact that the clauses in claim 21 are written in classic "means-for" language. As such, each of the clauses describing:

(1) a means for producing a forward beam and a backward beam from at least one infrared source,

(2) a means for producing a sample beam and a reference beam from said forward and backward beams, and

(3) a means for producing a null signal from said sample and reference beams,

should be read according to 35 USC §112, ¶6. As the Examiner is surely aware, in examining the claims this requires turning to the specification of the patent application and considering the specific structure corresponding to the recited functional language in connection with each means:

The various structural features required by the means clauses recited in claim 21 are found in figures 2 and 3. Neither of these particular setups is believed to be disclosed in nor fairly suggested by Mattson.

In view of the foregoing, the rejections under Mattson should be withdrawn as to 1-10, 12, 13 and 21-28.

Should the Examiner consider the situation to be otherwise, however, he is reminded that a reference anticipates a claim only if it discloses (either expressly or inherently) every limitation of the claim. *Verdegaal Bros., Inc. v. Union Oil Co.*, 814 F.2d 628, 631 (*Fed. Cir.* 1987). Stated in another way, numerous cases stand for the proposition that unless all of the same elements are found in substantially the same situation and united in the same way to perform the identical function in a prior art reference as the claimed invention, there can be no anticipation. See, *Application of Merechang*, 575 F.2d 865 (C.C.P.A. 1978); *Application of Stauffer*, 254 F.2d 127 (9th Cir. 1957); *Application of Bain*, 331 F.2d 974 (6th Cir. 1964); *Application of Greening Nursery Company*, 376 F.2d 738 (8th Cir. 1967); *Application of Dunlop company*, Ltd., 484 F.2d 408 (6th Cir. 1973) and *Kori Corporation and H.J. Rivet*, 708 F.2d 151 (5th Cir. 1983).

In rejecting a claim under 35 USC §102, it is incumbent on an Examiner to provide such reasoning as needed for the applicant to judge the propriety of continuing prosecution. 35 USC §132. Accordingly, if the rejection of any of claims 1-10, 12, 13 and 21-28 is to be maintained, Applicants respectfully request that the Examiner set forth a full case for such anticipation, as opposed to merely asserting that the claims are anticipated or "clearly" anticipated without further reasoning or support for the position. In view of the foregoing, Applicant sees no evidence of anticipation at all; much less, clear evidence.

Claims 1-13 and 21-28 in view of Griffiths et al. (Chapter 8-A0).

In reference to figures 8.9-8.15 of Griffiths, claims 1-13 and 21-28 were also rejected as clearly anticipated.

The same arguments made above with respect to Mattson hold for Griffiths. As to the method claims 1-13, Griffiths neither discloses nor fairly suggest the acts of method claims 1-20 with a sample of low transmissivity. The teachings of the reference regarding the type of the sample to be observed are found at page 298 in discussing the use for low concentration (and hence high transmissivity) samples and at page 308-310 discussing the typical use of the technology described in connection with weakly absorbing (*i.e.*, high transmissivity) sample. At page 285, the article similarly states that the dual beam technique described was developed to allow ". . . an interferogram to be measured that is due only to the small amount of radiation absorbed by the sample . . . ."

As to system claims 21-28, upon the proper application of 35 USC §112,¶ 6 to the language of claim 21as urged above, it is apparent that nothing shown or described in Griffiths anticipates the structural requirements of those claims. In addition, the specific requirement of claim 28 for inclusion of low-transmissivity sample, and those of 25-27 regarding the nature of the reference cell are absent from Griffiths.

In view of the foregoing, the rejections of claims 1-13 and 21-28 over Griffiths should be withdrawn.

Rejection under 35 USC §103

Claims 14-20 were rejected as obvious over Griffiths. In formulating the rejection, the Examiner stated that it would have been obvious for one of ordinary skill in the art to inspect any type of material sample and use a reference which will provide the best null in relation to the sample tested. The Examiner asserted that any such sample and reference would have no effect on the apparatus or the method in which it is used.

Actually, contrary to the Examiner's position, use of the specific systems and methodology referenced in Griffiths would prove ineffective unless both are changed significantly in order to accommodate samples of low transmissivity (including physiological samples). Griffiths does not contemplate the use of reference materials that could be used to provide adequate nulling of low transmissivity samples. As such, the apparatus of the Griffiths system would need to be changed in at least this respect in order to function according to the present invention. Such an alteration (involving the careful selection and adjustment of the composition of the reference material and beam path through the reference material) would alter not only the apparatus, but also the methodology employed by the Griffiths system. These alterations would render the system unsuitable for carrying out the optical subtraction techniques applied to gaseous and solid samples referenced at pages 309 and 310.

According to MPEP § 2143.01, where the proposed combination/modification would render the referenced invention being modified unsatisfactory for its intended purpose (in this case, quantifying analyte present in a gaseous or solid sample as taught therein), then there is no suggestion or motivation to make the proposed modification. See, *In re Gordon*, 733 F.2d 900 (Fed. Cir. 1984).

Even if this were not the case, Applicants posit that the Examiner is engaging in impermissible hindsight. Applicants are the first to teach 1) not only using the methodology disclosed for a low trasmisivity sample, but 2) also where the particular sample example given in claim 14 as a physiological sample. Additionally, Applicants are the first to teach using the methodology disclosed for a low trasmisivity sample in detecting glucose as set forth in claim 20. Applicants assert that it was not common knowledge to those with skill in the art that the Griffiths systems and techniques might be tried on any and all sample types. The text of Griffiths at 298 and 308-310 cited above actually indicates otherwise – it speaks of applicability in only particular situations –and never, to Applicants' knowledge, in a generic sense. Unless the Examiner can demonstrate that those with skill in the art appreciated broader applicability of the Griffiths teaching, then the rejection should be withdrawn. *See*, MPEP §2145 (X)(A).

In addition, the motivation voiced by the Examiner to make such a leap from the teachings of the Griffiths reference (never before used for such purposes as Applicants claim) as being a matter of simply inspecting any sort of sample, is a blatant example of an "obvious to try" rationale. *See*, MPEP §2145 (X)(B). In the event the present rejection as is to be maintained, Applicants respectfully request that the Examiner carefully explain how merely formulating a rejection stating that it would be "obvious to one with ordinary skill in the art . . . inspect any type of material sample . . ," is anything but a mere invitation to try approaches that are not suggested and made without any regard to prospects for success. See, *In re O'Farrell,* 853 F.2d 894-903 (Fed. Cir. 1988).

It is with respect to the last point, that Applicants place particular emphasis. As contemplated by MPEP §2144.08 (II)(A)(3)(e), some reasonable expectation of success is required in making the proposed modification, else no *prima facie* case of obviousness has been established. If the Examiner is not able to provide a reference establishing that such an expectation is reasonable, the rejection should be withdrawn unless the Examiner is prepared to provide a showing in accordance with MPEP §2144.03.

As a corollary to Applicant's assertion that there would be no reasonable expectation of success as to the modification of Griffiths proposed by the Examiner, it is asserted that what Applicant have taught (and claimed with respect to low transmissivity samples, biological samples and glucose

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detection) using dual-beam FTIR techniques is contrary to conventional wisdom, because prior dual-beam FTIR approaches known to Applicants only deal with low absorptivity, high transmisivity samples. This too weighs in factor of patentability. *See* MPEP §2145(X)(D)(3).

While each of the above arguments are most clearly directed to obviousness of the type of sample used and analyte to be detected, the comments regarding impermissible hindsight and "obvious to try" rationale are also applicable the additional subject matter of claims 16-19. Nothing in Griffiths teaches nor even remotely suggests using water of any sort as a reference material, or a variable pathlength for a reference.

For the foregoing reasons, claims 14-20 are believed nonobvious in view of Griffiths along with those claims (claims 1-13) rejected as anticipated by Griffiths. Accordingly, allowance of these claims is respectfully requested.

IN CLOSING

Applicants respectfully request reconsideration of the application in view of the amendments and remarks made herein. No new matter has been added.

Applicant submits that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number LIFE-005.

Respectfully submitted,
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VERSION WITH MARKINGS TO SHOW CHANGES MADE

1. A method of determining the concentration of an analyte in a sample of low transmissivity, said method comprising:

providing a sample of low transmissivity;

[(a)]producing a sample beam from [a] said sample of low transmissivity and a reference beam from a reference;

[(b)]producing a null signal from said sample and reference beams; and

[(c)]deriving the presence of said analyte in said sample of low transmissivity from said null signal.

6. A method of determining the concentration of an analyte in a sample of low transmissivity, said method comprising:

providing a sample of low transmissivity;

[(a)]producing a sample beam from [a] said sample of low transmissivity and a reference beam from a reference using forward and backward beams produced from at least one infrared radiation source;

[(b)]producing a null signal from said sample and reference beams[, with the proviso that said steps (a) and (b) further comprise passing light through an interferometer]; and

[(c)]deriving the presence of said analyte in said sample of low transmissivity from said null signal;

wherein each of said beams pass once through an interferometer.

11. The method according to Claim 6, wherein said method further comprises:

[(a)]producing a forward beam and a backward beam with an interferometer from a single infrared radiation source;

[(b)]directing said forward beam into said sample of low transmissivity and directing said backward beam into a reference and collecting a sample beam and a reference beam, respectively;

[(c)]combining said sample and reference beams to produce a nulled beam;

[(d)]detecting said nulled beam with a single detector to obtain a detected null signal; and

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[(e)]deriving the presence of said analyte in said sample of low transmissivity from said detected null signal.

16. The method according to Claim [6] 14, wherein said reference comprises water.

12. The method according to Claim 6, wherein said method further comprises:

[(a)]producing a forward beam and a backward beam from at least one infrared radiation source;

[(b)]directing said forward beam through said sample of low transmissivity and directing said backward beam through a reference to produce a sample beam and a reference beam, respectively;

[(c)]introducing said sample and reference beams into an interferometer and producing a null signal from said sample and reference beams following their exit from said interferometer; and

[(d)]deriving the presence of said analyte in said sample of low transmissivity from said null signal.

21. A dual beam infrared spectrometer [device] system for use in determining the concentration of an analyte a sample of low transmissivity, said [device] system comprising:

means for producing a forward beam and a backward beam from at least one infrared source;

means for producing a sample beam and a reference beam from said forward and backward beams; and

means for producing a null signal from said sample and reference beams.

22. The [device] system according to Claim 21, wherein said [device] system further comprises an interferometer means.

23. The [device] system according to Claim 21, wherein said device further comprises a means for deriving said analyte concentration from said null signal.

24. The [device] system according to Claim 21, wherein said [device] system further comprises a reference.

25. The [device] system according to Claim 24, wherein said reference is a variable path length reference.

26. The [device] system according to Claim 24, wherein said reference comprises a liquid.

27. The [device] system according to Claim 24, wherein said reference comprises a solid.

28. The [device] system according to Claim 21, wherein said [device] system further comprises a sample of low transmissivity.